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AT

DEPARTMENT OF HEALTH AND HUMAN RESOURCES

FOOD AND DRUG ADMINISTRATION

TITLE III REGISTRATION AND PRIOR NOTICE TELECONFERENCE

Wednesday, January 29, 2003

1:00 p.m.

16071 Industrial Drive
Gaithersburg, Maryland

02N-0276
02N-0278

TR1

MILLER REPORTING CO., INC.
735 8th STREET, S.E.
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Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

Title III Registration and Prior Notice Teleconference
January 29, 2003

Errata Sheet
for the official transcript*

The following changes in the transcript are submitted.

Page 1, department name (first line):

Current: Department of Health and Human Resources
Correct: Department of Health and Human Services

Page 2, Panel I name:

Current: Panel I - Registration and Facilities
Correct: Panel I - Registration of Food Facilities

Page 9, line 18:

Correct: Registration of Food Facilities

Page 9, line 20:

Correct: our first panel on Registration of Food Facilities. It

Page 17, line 14:

Correct: chewing gum, and components of these articles.

Page 31, line 10:

Correct: complete all the required fields.

* Please note that the page and line number references in this errata sheet correspond to the *official printed* version of the transcript. The page and line number of text in the electronic version does not match the page and line number of the same text in the official printed transcript.

Page 42, line 4:

Correct: your comment will come into this docket and be

Page 76, line 7:

Correct: purposes, would be that of the washing, the peeling, and

Page 84, line 9:

Correct: on that shipment, we may not have had someone

Page 85, line 20:

Correct: notice or three hours or more

Page 88, line 7:

Correct: MR. BRUSH: Well, let's talk about what

Page 95, line 14:

Correct: which is tied to facilities, but they

Page 104, line 17:

Correct: anything that is handled on a highly expedited JIT

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C O N T E N T S

P R O C E E D I N G S

Introductory Remarks

MR. BARNETT: Welcome to this live video teleconference. I am Mark Barnett of the U.S. Food and Drug Administration and I will be serving as your moderator this afternoon.

Today we are going to talk about two important regulations that are being proposed by the FDA that will help protect our nation against bioterrorism. Both of those regulations concern food and animal feed products regulated by the FDA.

One of the regulations would require the registration of domestic and foreign food and animal feed facilities. The other would require prior notice of imported food shipments into the United States.

Our broadcast today is being received live throughout the United States and South America, and in Canada, Mexico, and the Caribbean. Our audience includes manufacturers, processors, packers, holders, distributors, and transporters of food and animal feed products. In addition, this program is

being seen by importers, agents, brokers, and representatives in various embassies throughout the world.

We have two basic goals in doing this broadcast. First, we want to be sure that you understand these proposed regulations, why FDA proposed them and what they provide for. These regulations do not impose any requirements on you right now. They represent FDA's current thinking on what the final regulations would look like.

And that brings me to the second purpose of today's broadcast, and that is to encourage you to comment on these proposals before they are made final. That is very important. By sending us your comments, you can help to shape these regulations while they are still being developed.

Now, here is how the comment system works. Under U.S. law, proposed regulations are published in a document called the Federal Register. This provides a notice of what a U.S. Government agency is considering in a particular regulation, and it allows interested parties to submit comments or

suggestions to make the proposed regulation more effective or less burdensome.

Comments on proposed regulations are accepted for a specified period of time. They are carefully considered by the government agency proposing the regulation, and then later they are summarized and discussed in the preamble section of the final regulation, which is also published in the Federal Register.

We encourage you to send your comments on these two regulations to our Dockets Management Branch, either electronically or by mail. Throughout the broadcast today, we will be giving you information on how to do that.

You can also find information on how to submit comments by going to our Bioterrorism web page. Only comments submitted on time to our Dockets Management Branch are considered to be official comments.

Now, let me talk a little bit about the format for today's program. We are going to have two panels of FDA experts, the first one on

Registration of Facilities, and the second panel on Prior Notice of Imported Food Shipments.

We will have a 10-minute break between the panels and during the break, you will see important information on your screen about how to submit comments on these two regulations to our Dockets Management Branch.

I will be asking the panelists questions on what you will need to know about the proposed regulations. You will also have the opportunity to ask questions of the panelists, either by phone or fax or e-mail.

The phone number to call is 1-800-527-1401, the fax number is 1-888-361-4011, and the e-mail address is tvquestion@cdrh.fda.gov. Now, those numbers will be appearing on your screen right now, and they will reappear from time to time during the broadcast.

We can accept faxed or e-mailed questions in either English, Spanish, or French. If you choose to phone us, we can take only calls in English. Now, you have two choices for phone

calls, you can ask your question to the panelist directly on the air or you can leave your question with the person answering the phone, and it will be given to us along with the faxes.

Let me clear up a possible point of confusion about your questions. During this broadcast, we are encouraging you to ask questions of our panelists to be sure you understand the regulations, but you cannot use your communication with the panelists today as a means of submitting your comments on the two regulations.

As I said earlier, you have to send those comments either electronically or by mail to our Dockets Management Branch, and you will get information on how to do that during the break.

Before I introduce the first panel, I would like you to hear a few words of introduction from the Commissioner of the U.S. Food and Drug Administration, Dr. Mark McClellan.

DR. McCLELLAN: Last year, the President and Congress enacted legislation in recognition of the fact that we live in a new era, an era in which

there are real threats of terrorism to this nation. Those threats include potential dangers to our food supply. We now worry about food security, not just food safety, and the legislation included provisions to help prevent and respond to an attack on our food supply.

They included four specific components that will lead to new FDA regulations: First, a regulation on the registration of food producers, processors, and distributors; second, a regulation on prior notice of shipments of food coming into the country; third, a regulation on recordkeeping requirements; and, finally, a regulation on administrative detention.

I believe that meeting the new challenge of keeping our food supply secure in the face of terrorist threats is one of the most important challenges facing the agency today. The FDA is fully committed to implementing the new regulations that follow from this legislation by the statutory deadline of December 12, 2003.

I also know that this new legislation and

the regulations will have a significant impact on the way that business is conducted nationally and worldwide, and we are fully committed at the FDA to making sure that we implement these regulations effectively and in the lowest cost manner possible.

All of us, food producers, processors, distributors, importers, consumer groups, government agencies responsible for food safety, all of us have a vital stake in the success of this effort. The American people are counting on us to meet the challenge of keeping our food supply secure.

I want to thank you for participating in today's teleconference and I want to let you know that we at FDA look forward to working with you to meet this critical new challenge.

Panel I

Registration and Facilities

MR. BARNETT: We are back live and now for our first panel on Registration and Facilities. It is important to remember that this proposed regulation would require U.S. and foreign

facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. to register with the FDA, so this panel is going to be of particular interest to them.

Let me introduce our panelists.

Bob Lake is director of the Office of Regulations and Policy in the FDA's Center for Food Safety and Applied Nutrition.

Leslye Fraser is associate director for Regulations in that office.

Lana Ogram is director of the Division of Compliance Policy in the Office of Enforcement with FDA's Office of Regulatory Affairs.

Dr. Ray Russo is director of the Division of Software Engineering Services in FDA's Office of Management and Systems.

Bob, let me begin my asking you about the timing for this. I know that these two regulations were right up to the wire, that scheduling was very tight. As of yesterday, they were not published or about to be published or whatever.

Where do we stand right now at this

moment?

MR. LAKE: Both documents, Mark, have now been cleared for publication. Both documents that we will be talking about this afternoon were put on display at the Federal Register this morning, and by the beginning of this broadcast, they were also supposed to be put on FDA's web site, as well, so they are now publicly available.

MR. BARNETT: Thank goodness, for this broadcast.

Anyway, let me ask you to begin by talking about why FDA is requiring this registration regulation.

MR. LAKE: Well, first, as the Commissioner just noted a moment ago, the new Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which we, for short, simply refer to as the Bioterrorism Act, specifically requires that we publish these proposals that we are talking about this afternoon, as well as others.

But in addition to that, the more

meaningful understanding of what they do is that the registration proposal, along with the others, will better enable FDA to respond to situations where there is a foodborne outbreak and to then get the dangerous food off the market as quickly as possible.

The other benefit that we see in the registration is that it will enable FDA to more quickly contact the various segments of the industry when that becomes necessary. For example, if we received information indicating that there was a credible threat of a terrorist act against a particular set of food industries or types of facilities, this registration information would enable FDA to quickly contact those facilities and pass on the information they would need to protect themselves.

MR. BARNETT: It is really two-way communication then, the FDA is getting information, but then it is quickly passing it back to the industry as a result of this.

MR. LAKE: We see both of these as being

of value, yes.

MR. BARNETT: Leslye, let me ask you, who is it that has to register under the proposed regulation?

MS. FRASER: Mark, both the Bioterrorism Act and the proposed rule would require owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the FDA.

The proposed rule includes definitions for each of these terms, but briefly, manufacturing and processing we are defining together as combining one or more ingredients into a food product. Packing is placing food into a container without changing the form of the food, and holding could also be considered storing, such as in a warehouse, a silo, or a grain elevator.

With respect to domestic facilities, they would have to register if they manufacture, process, pack, or hold food even if that food does not enter interstate commerce.

MR. BARNETT: Lana, a lot of facilities and firms are already registered either with the FDA or with another government agency.

If they are already registered in that way, do they have to do this again?

MS. OGRAM: Yes, they do. The Bioterrorism Act requires that facilities register with the Food and Drug Administration even if they have previously registered with FDA or other government agencies under other requirements, and there are a couple of reasons for this.

One is that information submitted under other registrations can vary quite significantly, and those registrations would not be for the purpose that this one is, and that is for administration under the Bioterrorism Act.

Another very important reason is that this information must be quickly accessible to FDA in the event of an emergency. If that data is owned by another government agency, there could be delays in accessing it.

MR. BARNETT: And, of course, speed is

really a key for this particular purpose in bioterrorism.

MS. OGRAM: Extremely important.

MR. BARNETT: Leslye, you used the word facility. Define that so people can understand that as opposed to similar words.

MS. FRASER: We are proposing a definition of facility as a structure or structures in one general physical location under one management, or in the case of a mobile facility, one that travels to multiple locations, and again it is a facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States.

MR. BARNETT: If I am a company and I have several facilities in several parts of the country, can I register once as company or do I need to register for every one of those facilities?

MS. FRASER: You would need a registration for each facility whether, as a company, you have those facilities in the United States or worldwide.

DR. RUSSO: Mark, in order to make that

easier, the electronic Internet-based registration system is being designed so that an owner of multiple facilities can complete a registration form for each facility without having to re-enter any item that is the same for all the facilities, like, for example, the name of the owner of the facility.

MR. BARNETT: Leslye, does that include facilities for all foods?

MS. FRASER: Most foods. There are some foods that are regulated by the U.S. Department of Agriculture, and that is meat and poultry and egg products, and the facilities that are exclusively dealing with those food products would not be subject to these requirements.

Facilities, though, that are manufacturing, processing, packing, or holding food under FDA's jurisdiction would have to register, and if a facility has food that is under FDA jurisdiction and USDA's jurisdiction, they also would have to register.

MR. BARNETT: They still have to register.

Well, we have narrowed it down now, Leslye, to FDA-regulated foods, but for those people who don't know what those foods are, can you give us some examples? It's a pretty broad spectrum.

MS. FRASER: It is a broad spectrum. What is important to remember is that the Bioterrorism Act amended FDA's current statute, the Federal Food, Drug, and Cosmetic Act, and that Act has a definition of food that FDA has implemented for many years, and that is the one that applies here. Namely, that definition is food is defined as articles used for food or drink for man or animals, chewing gum, and components of these animals.

What you will see in the proposed rule is just to make sure everyone understands the scope and the breadth of the food that FDA regulates. We have included a number of examples, and I will kind of go through them fairly slowly - fruits and vegetables, fish and seafood, dairy products, eggs, raw agricultural commodities for use as food or components of food, canned foods, animal feed

including pet food, food and food ingredients.

Food also includes food additives including substances that migrate into food from packaging and other articles that contact food, dietary supplements and dietary ingredients are considered food, as is infant formula, beverages including alcoholic beverages and bottled water, live food animals, such as hogs or elk, and then my personal favorite, bakery goods, snack foods and candy.

MR. BARNETT: Okay. Now, you said that facilities that work with FDA-regulated foods have to register, those with USDA-regulated foods don't, but there are other exceptions, aren't there? Are there facilities that don't have to register besides that?

MS. FRASER: Yes, there are. The proposed rule does include a number of other exemptions that were provided in the Bioterrorism Act, and as you will see on this slide, they include farms, retail food operations that sell food directly to consumers, restaurants, and this includes things

like cafeterias, bistros, and what you would normally think of as restaurants, and then by analogy, because the food includes animal feed, facilities that serve food to animals, like pet shelters, would be exempt as, quote "a restaurant."

Nonprofit food operations are exempt, fishing vessels that do not process fish would be exempt, and then there is a provision that if you are a foreign facility that manufactures, processes, packs, or holds food, and food from your facility goes to another foreign facility for further processing or packaging before it comes to the United States, that first foreign facility would not have to register.

MR. BARNETT: Now, that last one is very interesting and it may lead to some questions from our audience.

If I am the first processor in a series of processing steps, how do I know whether I am exempt because the next person does the significant processing, or how do I know, conversely, that I am the last step and therefore I should be

registering?

MS. FRASER: That's a good question. We have two slides that sort of give an example of this. Basically, you would know because you would know what is the form of the food that you are making, and you would know where you are sending the food.

So, if you look at the top example, we have the first foreign facility, and it is making a food product. If that facility packages it itself, and then sends it to the United States, well, then it is basically the last foreign facility that has done a major activity to that food is the one that has to register.

But if, instead, the foreign facility takes its food product and it sends it to a different foreign facility, either in its country or another country outside the United States, and then that facility does some further processing, and then they send that food product or food ingredient to the United States, then, the first foreign facility would not have to register because

it is not the last in that chain.

If we go to the next slide, you will see that, you know, we kind of succinctly summarized it, that if you are manufacturing or processing a finished food product, and you are a foreign facility, you register.

If you are packing or holding a food product or food ingredient, you register, but if you are manufacturing or processing a food or a food ingredient, and it is going to another foreign manufacturer, then, you are exempt.

MR. BARNETT: Okay. What about a facility that does a mixture of activities, that is, some of them would fall into the category of exempt, some of them would fall into the category of register, they have to register then?

MS. FRASER: Yes, they would have to register that part of their activity that would be subject to FDA's jurisdiction or has a covered activity. An example of this could be a grocery warehouse that sells food to consumers directly, but it also may sell food to other retailers, maybe

the mom and pop shops. In that case, they would have to register that part of their facility that is not selling food directly to consumers, because in the proposed rule, we define a retail facility as one that sells food directly to consumers only.

MR. BARNETT: Let me give you another example. Suppose I am a farmer, I grow oranges, and some of those oranges are converted on my facility, on my farm, to orange juice, do I register?

MS. FRASER: That is a little more difficult to answer, and it is going to turn on what you are doing with the orange juice. The farm aspect, the farming activities are exempt, and most farms will remain exempt because they are engaged in traditional farming activities.

In the proposed rule, as you will see on the slide, we defined a farm as a facility in one general location, that is devoted to the growing of crops or the raising of animals, or both, and animals does include seafood, so fish ponds would be considered a farm.

There are some other examples of farms, like apple orchards, hog farms, fairy farms, feed lots, and so forth, so it depends as a farm. If you are a farm and you are doing traditional activities of packing and holding food that you grow on the farm or raise on the farm, if you are consuming all the food on that farm, you are still exempt, or, in your case, with the orange juice, if you are manufacturing and processing the oranges you grow on your farm, and making orange juice on the farm, but you are still consuming all of the juice on the farm or another farm that you own, we still would say you are exempt from registering.

Where it would get to the point that you would be covered is if you take your oranges and then process them into orange juice on the farm, and you sell it to a distributor who would then sell it into commerce.

MR. BARNETT: Then, you register.

MS. FRASER: Then, you register because now you are a processor, you register the orange juice facility, the farm still remains exempt.

MR. BARNETT: Right. We are talking so far, Leslye, about who has to register, but now I want to talk about what information do you have to provide when you register.

MS. FRASER: The information that you have to provide is taken from the Bioterrorism Act in large part, and the information that is required is the name of the facility, its full address, the phone number, the fax number if it's available, and an e-mail address if the facility has one. If the facility is owned by a parent corporation, then, we need that same information for the parent corporation.

We also would look from the facility for the emergency contact person's information, and that would include the name, their title, their office number, their home phone number, and their cell phone number if they have one, and e-mail address.

Again, as it says, this is for use in emergencies, and as Lana was talking about and Bob was talking about earlier, if we have a threat that

we know about, actual or threatened, on a particular facility or a particular food product, we want to be able to get into touch with the contact people at these facilities.

You will see in the proposed rule that the emergency contact person does not have to be at the facility. A company, for example, could choose to have a senior corporate official who is responsible for all emergency operations be listed there.

They also need to provide a statement that everything they provided is true and accurate, and that person registering is authorized by the facility to do so.

Then, the last requirement is for foreign facilities, the Bioterrorism Act requires them to have a United States agent, and so we ask for information of their U.S. agent.

MR. BARNETT: To talk about the U.S. agent, anybody can't be a U.S. agent. What are the qualifications?

MS. FRASER: The qualifications that we are including in the proposed rule are similar to

the ones that we have for U.S. agent in our drug regulations that are existing now, and those are that the person has to reside or maintain a place of business in the United States. Other than that, the facility can choose the person that they want to be their United States agent who meets those qualifications.

MR. BARNETT: Now, all of the information you have talked about so far is required under the regulation, but I am sure there is information that the FDA would like to have voluntarily that might help in the event of a bioterrorism attack.

If so, if people want to provide that, what would it be, for example?

MS. FRASER: That is correct, Mark. We are asking for additional information, some of which FDA is asking for because it will assist us in communicating with facilities, not just in the event of an emergency, but say, for example, we have new regulations or guidance documents coming out, we can communicate directly with the affected facilities about those requirements or suggestions

that we are providing.

Other information that we are asking for in the optional category is information that is responding to comments we receive during the early outreach period we conducted from facilities, so I will go through those in a little bit.

The point I want to underscore is that this information is in addition to what is required, it does not replace what is required.

But what we have asked for is preferred mailing address. This is something a facility or a firm can choose to provide. A number of companies told us that they want to have corporate headquarters, for example, register all of their facilities, so this would allow them to list the mailing address that would be the place we would contact.

Type of activity, we are asking for the facility to let us know whether they manufacture, process, pack, or hold food, and again, if we have a threat that it is a manufacturing plant of canned vegetables, we would be able to target our

communications there.

Additional food product categories, the Bioterrorism Act limits the categories to those that are in our existing regulations, yet, there are additional foods that would be important for us to know about that aren't in those regulations, and they include dietary supplements, infant formula, and animal feed. So, we are asking facilities to provide that information to us.

Type of storage addresses warehouses. We are asking them to tell us are they a cold storage or what kind of storage facility, and again it is to help us target our communications.

The most all food product category again is in response to what facilities requested. Rather than have to check off many categories if they handle many food products at their facility, they can choose to check this one box and skip over the other mandatory. That is the one place where they would not have to complete the mandatory section.

Then, lastly, we are asking that if a

facility is a seasonal business, for example, it is only open in the summer, to let us know because that way when we are targeting communications, we would know that they are not open at that time.

MR. BARNETT: Okay. Let me pause for a moment and talk to our audience. If you have any questions about registration, send them in now. You have got the phone and fax and e-mail addresses.

We have about 30 more minutes for this panel, so you still have time to get questions in. I urge you to do that, and the number is on the screen right now, so get your questions to us.

In the meantime, I will continue with my questions and that is, to ask you, Leslye, what is the deadline for registration?

MS. FRASER: The Bioterrorism Act requires all facilities to be registered with the FDA no later than December 12th of this year.

MR. BARNETT: But when they can register, when can they start registering?

MS. FRASER: Our goal is to have

facilities begin registering on October 12th of 2003. Our intent is to publish a final rule and have our electronic system operational by that date, and we will publish the final rule in the Federal Register.

If for some reason we are unable to complete the final rule or the electronic system isn't operational then, we still will publish a notice in the Federal Register that lists the mailing address where registrations should be sent since again the Act requires all facilities to be registered even if we fail to issue regulations on time.

Lastly, I will just note that we do not want any registrations at this time. We will not accept the registrations that come in before we publish that final notice or rule.

MR. BARNETT: Ray, we have talked about what kind of information to provide and when to provide it. Now, let's talk about how and where a person registers. How do you do it?

DR. RUSSO: Well, Mark, electronic

registration via the Internet is FDA's preferred method. Electronic registration will benefit both food facilities and FDA in a number of ways.

The electronic system will accept registration forms 24 hours a day, 7 days a week from anywhere in the world via link off the FDA web site. The electronic system will help people prepare correct forms for submission. For example, the electronic system will not allow someone to not complete all the required forms.

MR. BARNETT: So, it almost assures that you do it right.

DR. RUSSO: To some extent, yes, it will be a help. Probably most important for registrants will be the fact that the electronic system will provide confirmation of registration and the registration number immediately.

So, electronic registration should be relatively simple and quick.

MR. BARNETT: Now, what if I am a firm that can't access the Internet for some reason?

DR. RUSSO: Well, Mark, in this era of

globalization, most facilities, both domestic and foreign, have access to the Internet, usually within their own company, but also through public libraries, schools, Internet cafes, commercial copy centers, but if it does turn out that a facility does not have reasonable access to the Internet, FDA will accept paper registrations.

Registrants should be aware, however, that the paper process could be slow. It could take several weeks, even several months, to get a paper registration processed depending on the mail systems involved and the number of paper forms that FDA has to process.

I mean, to illustrate, a facility would have to acquire the paper form, fill it out and mail it in. It has to come through the mail system to FDA, where is has to be received, opened, it has to be evaluated for correctness. If it is incomplete or illegible, FDA will have to mail it back to the facility, will have to travel back through the mail system. You are going to have it open it, correct it, send it back in again, so it

will come again for reevaluation of correctness. If it is again not correct, then, it would repeat that process.

If it is correct, FDA still has to prepare a confirmation notice and a registration number and mail it back to them. In addition, things often, well, sometimes will get lost in the mail or in handling, so there is some uncertainty with that.

That is why FDA's preferred method is the electronic registration system, which should be more certain and certainly simpler and quicker.

MR. BARNETT: Leslye, it is abundantly clear from what Ray just said that the paper method of registration is probably not desirable. Now, if I am a firm that despite the fact that there is an Internet cafe, I can't get to the Internet for some reason, is there a way that I can avoid paper registration, and not use the Internet myself?

MS. FRASER: Yes, FDA was very concerned of being able to make sure all facilities, both domestic and foreign, could register electronically as much as possible, so one of the things that we

have done is allow a foreign facility, at their choosing, to designate their United States agent as their agent in charge for purposes of registering the facility.

So, in this case, the facility could send their information to their U.S. agent, whether it is by mail or by fax, but they would send it to their United States agent, and again that person has to reside or maintain a place of business in the U.S., so they could go to the same places that Ray was talking about, the Internet cafes, the public libraries if they didn't have Internet themselves, and thereby register electronically and receive a faster receipt of confirmation than waiting to have it come through FDA.

One thing that we recommend in the proposal, it is not a requirement, but we do recommend that foreign facilities that choose to authorize their U.S. agents to act in this manner, to sign a written agreement with that agent for their own protection and the agent's protection, so the duties are clearly specified, and FDA does not

need to see a copy of that agreement.

MR. BARNETT: Ray, what about a fee for registration?

DR. RUSSO: There is no fee, Mark.

MR. BARNETT: Let's talk about updating registrations, things change, information changes, and I am sure that the FDA wants up-to-date information.

How do you do updates and when do you do them?

DR. RUSSO: Good question, Mark. FDA is proposing that any previously submitted registration form be updated within 30 days of any change to its information. If a facility is canceling its registration, it must submit a cancellation of registration form.

Both of these, the update and the cancellation of registration can be done electronically.

MR. BARNETT: Bob, talk about the significance a little bit about getting your firm registered with the FDA. Does this in some way

imply an approval or sanction by the agency of this particular facility?

MR. LAKE: No, Mark, it does not. The fact that the FDA has issued a registration number does not mean--well, it only means that we have actually received the information and that it's complete, and have given a number. It does not in any way mean that we have evaluated the facility or its products. It in no way constitutes an endorsement of the facility or its products.

MR. BARNETT: Lana, so far we have talked about who has to register, we have talked about the kinds of information, we have talked about how to register, how to change the information. Let's now start talking about the other end of that, and that is, what is FDA going to do with the information.

MS. OGRAM: As Bob mentioned earlier, it will allow the agency to rapidly notify any affected facility in the event that FDA receives information about a potential contamination of a food or in the event of an outbreak of a foodborne illness.

In addition to that, it will help FDA to work more effectively with other agency counterparts on a federal, state, and local level, as well as the affected facility and its distribution system, to prevent the contamination or to limits its impact on the public.

MR. BARNETT: One of the things that some firms I know are going to be worried about is when they submit this registration material to the FDA, is that going to be made available to the public?

MS. OGRAM: No, the Bioterrorism Act specifically states that this information in the registration system, which would include the identity of a facility or its location, will not be available to the public under the Freedom of Information Act.

MR. BARNETT: What about the possibility that the FDA could share the information with another government agency or with the states?

MS. OGRAM: That is definitely possible to do, and that is not considered a sharing of information with the public. FDA can share that as

long as we follow our regulations and procedures under this area.

MR. BARNETT: Well, I know that firms will be now asking the question, how do we know that the other federal agency or the state isn't going to, in turn, share that with the public, make it public?

MS. OGRAM: That's a very good question, and our regulations do require that we obtain written assurance from the agency receiving the information that they will maintain the confidentiality of the commercial or trade secret information that we provide to them.

MR. BARNETT: Well, let's talk about consequences now. What happens if FDA finds out that a facility is not registered?

MS. OGRAM: The Bioterrorism Act, in addition to the other provisions of the Food, Drug, and Cosmetic Act, give us a number of enforcement tools to deal with the situation in which a facility has failed to register.

The Bioterrorism Act specifically makes

failure to register a prohibited act, and then the other provisions of the Food, Drug, and Cosmetic Act give us the authority to file a civil or a criminal action against an individual who has committed a prohibited act, and that might take the form of an injunctive action or a prosecution.

MR. BARNETT: What happens if an import arrives and there is no registration for that company, but the material is here, it's at the port?

MS. OGRAM: The Bioterrorism Act specifically requires that that food be held at the port of entry unless FDA directs its movement to a secure facility.

MR. BARNETT: Who pays for that, who pays for all that storage?

MS. OGRAM: The proposed regulations will require that the consignee, owner, importer, or purchaser of the food will be responsible for the movement of the food to a secure facility, as well as the storage fees associated with that movement.

MR. BARNETT: Go ahead, I am sorry.

MS. OGRAM: And that movement will have to occur under bond.

MR. BARNETT: Bob, we have, the FDA has arrangements and agreements and understandings with NAFTA, the World Trade Organization. Very briefly, does this registration have any effect on that?

MR. LAKE: No, Mark, it has no effect on our obligations, but we have considered our obligations under the World Trade Organization and North American Free Trade Agreements. We are fully aware of those requirements, we are complying with them.

Now, the other thing I would note is that we are taking steps to make our computer interface with both this and the other proposal user-friendly, so that it is easy for all parties, foreign and domestic, to comply, and in addition to that, we are doing what we can to make compliance with these new requirements as easy as possible, as least burdensome as possible, consistent, of course, with the requirements to protect the American people.

So, we do believe that we are in full compliance with our trade obligations.

MR. BARNETT: Okay. Let me give you the logistic situation now. We have about 15 more minutes for this panel. I have one more question to ask you, and I have, I am happy to say, a pile of faxes from our viewers, so let me ask you my final question. I hope you keep your answer fairly brief, and then we will dig into these.

My last question is what is coming, what are the next steps in this registration regulation?

MR. LAKE: Okay, Mark. The most important thing is that the people reviewing and others who are interested in these proposals to submit their comments to the Food and Drug Administration during the comment period, which will be for 60 days.

We will consider all those comments, in fact, we are required to consider every issue raised by the comments before we issue the final regulation. We will, of course, be--or when you submit your comments, it is, of course, important that you identify the docket number associated with

the proposal.

In this case, the docket number is 02N-0276. Using that docket number assures that your comment will come into this document and be reviewed by the Food and Drug Administration.

Also, on the screen now I believe is a reference to the FDA web site where these documents can be reviewed and other information obtained.

MR. BARNETT: Okay. Now, let me start in on some of these faxes, and I am simply going to ask you to raise your hand if you want to respond.

This one says do importers who do not repack or store have to register?

MS. FRASER: The rule applies to facilities, not to persons, so if it is a facility that is manufacturing, processing, packing, or holding food in the United States or abroad except for those exceptions and exemptions, they would have to register, so it is not an importer, it would be the facility.

MR. BARNETT: Okay. The next one says I am confused about FDA's role in regulating live

animals, such as elk or live hogs. Aren't these animals regulated by USDA? How do the registration requirements pertain to live animals?

MR. LAKE: I will respond to that. The Department of Agriculture Food Safety and Inspection Service is responsible for regulating the slaughter and subsequent handling of meat and poultry products, but while the animals are still alive, they are under the jurisdiction of the Food and Drug Administration and always have been.

In addition to that, there are many game meats that fall outside of the USDA system that have always been regulated by FDA.

MR. BARNETT: The phone and fax numbers are up on the screen. You still have some time. We want more of these. We have got a big pile and we want even more, so get your questions in.

Here is another one. Would a foreign food packer or processor be required to register if it sells the food to a distributor within the foreign country with the intent that the food will be consumed in the foreign country and the distributor

later exports the food to the U.S.?

MS. FRASER: Well, the duty to register is for food that is consumed in the United States. Part of the requirements is that food from unregistered facilities may not be imported into the United States, so if the distributor is choosing to import food into the U.S., and the facility doesn't know about it, and the facility hasn't registered, the food will not be able to come in, and that is a requirement in the Bioterrorism Act.

So, that question, it would behoove the distributor to talk to the facility to make sure the facility is registered.

MR. BARNETT: Okay. Another one, and we have quite a few, so this is good, keep your answer fairly brief and we may make it. It is like a conductor on a train, we are going to get to Chicago maybe.

If all processing plants in a foreign country are registered with the competent--by the way, this one is from Australia--if all processing

plants in a foreign country are registered with the competent authority, that is, the government agency of the foreign country, and the foreign government--it's hard to read this--provides this list to the FDA, does each individual plant in that country have to register with the FDA?

MR. LAKE: The answer to that is yes. The Act specifically requires that these facilities register with the Food and Drug Administration if they are going to be sending food to the United States.

MR. BARNETT: Okay. Next. Are manufacturers, processors, packers, or holders of shell eggs required to register?

MR. LAKE: Yes, they are. Processed egg products come under the USDA, but shell eggs are still FDA.

MR. BARNETT: Okay. Please clarify the definition of food. For example, does it include food ingredients and direct food additives, as well as food contact substances?

MS. FRASER: Yes, it does. The definition

of food is very broad. It includes finished food products, as well as food ingredients and substances that migrate into food because they are part of the containers in which the food is held.

MR. BARNETT: When is an ingredient considered a food and when is an ingredient considered a non-food? Is a raw coffee bean a food or does it become a food only after roasting?

MR. LAKE: I will take that one. In the case of something like coffee, a coffee bean, although it is going to be further processed, it is ordinarily used only for food, and so we do now regard it, and would continue to regard it, as being a food at the time it is imported into the United States.

MR. BARNETT: Okay. If juice concentrate is extracted or concentrated in a foreign facility, is held, and then transported and shipped to the U.S., which facility is required to register, if any? Shall I read that again?

MS. FRASER: Yes.

MR. BARNETT: If juice or concentrate is

extracted and concentrated in a foreign facility, is held, and then transported via ship to the U.S., which facility is required to register?

MS. FRASER: The facility it is held--I am assuming from that question it is held in a different facility--and both would be required to register because it is a foreign facility that processes or packs, that manufactures, processes, packs, or holds food is required to register unless there is further processing or packaging.

So, storing it does not exempt the foreign facility that manufactured and processed it in the first place, nor does it relieve the subsequent facility that is holding it from registering. So, in that case, both would.

MR. BARNETT: Okay. Are facilities or firms that manufacture food contact or packaging materials subject to registration?

MR. LAKE: If at the time they are manufacturing the material, they know that it is going to be used for food use, then, that facility is required to register with FDA.

MR. BARNETT: Okay. This one says do trade names or product brand names or facility operating names--well, there is no verb there, so I don't know, I guess it means which name should they use?

MS. FRASER: The facility, in many cases, both, the facility has to register its name and then another piece of required information is the trade name.

MR. BARNETT: This one, I think you answered, and if you did, maybe we shouldn't do it again. It says how and when is updating information provided or required? I think we did that. You talked about that, so I think we will let that one go.

If domestic or foreign firms are already registered with FDA for other purposes, for example, drug registrations, is it necessary to re-register under Bioterrorism? I think you have pretty covered that one, as well.

Here is one from a consumer. It says as a mother of three small children, I have serious

concerns, not just about the safety of our food supply, but also about how quickly a recall can take place should the worst case scenario actually happen. Will someone please comment on that.

MR. LAKE: The new legislation does not have anything in it about recall, but it does have a number of things that will give FDA more information sooner, and armed with this earlier information, we believe that it will assist FDA in identifying problems and getting bad food off the market either through recall or other means.

MR. BARNETT: Do warehouse clubs, like Sam's Club, Costco, et cetera, have to be registered individually, since they oftentimes sell to other retailers?

MS. FRASER: Yes, this is a facility by facility registration, so each Sam's Club or Costco in that example would have to register just like any other facility engaged.

MR. BARNETT: Do farm markets or community farm markets need to register?

MS. FRASER: Many of those would fall

under the retail exemption if they are selling food directly to consumers, so the question would be who are their customers.

MR. BARNETT: Suppose I am an exempt company and I also donate food off site, for example, to a food bank and distributed locally, does this now require me to register?

MS. FRASER: That's a good question, and we would like to get comment on that one, because I don't think we have addressed that one specifically in the regulation.

MR. BARNETT: Do supermarkets that have central commissaries dedicated to their Own--capitalized--Own stores need to register?

MS. FRASER: If they are considered part of the retail exemption, if they are selling it to consumers, in this case, the consumers would be their employees, but they still would be consumers.

MR. BARNETT: Pet and animal shelters are exempt from the rule. Does that exemption apply to veterinary clinics that sell food to pet owners and use food during treatment or boarding?

MS. FRASER: Yes, they are exempt.

MR. BARNETT: A one-word answer with the time we have, that is really good.

As a food processor, what responsibility does my establishment have to confirm or verify that our vendors or suppliers are registered through FDA?

MR. LAKE: I will take that one. The only responsibility that any facility has is for its own actions, so it has to register itself, it does not have to take responsibility for the registration by anybody else.

MR. BARNETT: Do not, I wonder--oh, here is one.

Do companies already--you answered that one about, okay, about preregistration. Any plans to extend these requirements to cosmetic manufacturing establishments?

MR. LAKE: No. The law only covers foods, not cosmetics.

MR. BARNETT: What do you mean by a nonprofit food facility?

MS. FRASER: We have a proposed definition in the rule for that, but it is a facility that is exempt under current Internal Revenue Service regulations.

MR. BARNETT: Does the registration number have to be listed on the packaging?

MS. FRASER: No, it does not.

MR. BARNETT: Who does a foreign company list as its agent if they deliver directly to a retail facility?

MS. FRASER: The foreign facility has the obligation of deciding who it wants as its U.S. agent. The only requirement we are proposing is that that person reside or maintain a place of business in the United States.

MR. BARNETT: Will FDA send reminders of registration updates?

MS. FRASER: We are considering ways of reminding facilities that updates are due and looking for ways, so we are looking also for comments on how we can get facilities to provide timely updates.

MR. BARNETT: The pile is exhausted, and we have just a very few minutes. I don't think we are getting any more faxes right now, so what I am going to do is declare a break now, so we can change panels, and so on, so we are going to take a 10-minute break.

When we come back, we are going to proceed to the second panel on Prior Notice. Now, during the break, we are going to be showing you some important information on your screen. You will see the electronic and mail addresses you should use to submit your comments to the Dockets Management Branch, and you will see the Internet address for FDA's Bioterrorism web page.

On that web page, you will find a link to all of the comments received by FDA on these proposed rules. You will find updated information on future broadcasts, and a wide variety of topics on FDA's activities involving bioterrorism.

So, we will be back here in 10 minutes.

[Break.]

Panel II

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[Break.]

Panel II

Prior Notice of Imported Food Shipments

MR. BARNETT: Okay. We are back live and ready for our second panel, to discuss the proposed regulation on Prior Notice of Imported Food Shipments. Remember, this regulation focuses on all FDA-regulated food and animal feed. With this regulation, the obligation to comply rests with the importer, purchaser, or their agent, and so this panel is going to be particularly interesting to them.

Let me introduce our panelists.

Bob Lake, who was here for our first panel, is director of the Office of Regulations and Policy in FDA's Center for Food Safety and Applied Nutrition.

Leslye Fraser, who was also here during our first panel, is associate director for Regulations in that office.

Ben England is regulatory counsel to the Associate Commissioner for Regulatory Affairs in FDA's Office of Regulatory Affairs.

George Brush is project officer in the

Office of Information Technology in FDA's Office of Regulatory Affairs.

Bob, let me start with you again and ask you a similar question to the one that I asked the first time.

What is prior notice and why has FDA proposed doing it?

MR. LAKE: Again, as the Commissioner pointed out at the beginning of this telecast, the Bioterrorism Act of 2002 requires that we go through rulemaking on the prior notice requirements.

More importantly, though, I think is that the real value to FDA and to the American people of this proposed requirement is that it will provide FDA advance notice of what is coming to the U.S., where it is coming in and where it is coming from, and this will enable, better enable FDA to make judgments about what it is we look at, what we need to look at, so that we can meet it when it arrives, and we believe this will better enable us to protect the health of the American people.

MR. BARNETT: The first panel talked about registration, this panel is talking about prior notice. Very briefly, distinguish the two.

MR. LAKE: Yes. The previous discussion we had around registration focused on facilities, whether those facilities were in the United States or abroad. This proposal is not about facilities, but is rather about articles of food, which we will explain further as we go along.

Again, it is articles of food that are being imported into the United States.

MR. BARNETT: Leslye, the Bioterrorism Act actually doesn't specify who should submit the prior notice. So, under the regulations, who have you authorized to submit prior notice of shipments?

MS. FRASER: Yes, Mark, the Act did not specify and to avoid confusion, what FDA is proposing is that it is the purchaser, the importer who resides or maintains a place of business in the United States, is authorized to provide prior notice, or they can have an agent acting on their behalf also who resides or maintains a place of

business in the United States.

Then, for articles of food that are imported, transported in the United States to another port and then exported, they also have to have prior notice, but in that case, we are also authorizing the arriving carrier or the transporting carrier to provide the prior notice.

MR. BARNETT: Talk about the foods that are subject to this regulation on prior notice.

MS. FRASER: This is the same list of foods that were subject to registration and for those who will be viewing this tape live and maybe separately from registration, I will go through it again.

It is food that is in our current Federal Food, Drug, and Cosmetic Act. That is the definition that we are using, and that is articles of food used for food or drink for man or animals, chewing gum, and components of these articles.

Again, we have also included a list of examples of the breadth of food that FDA regulates just so that people understand what types of food

are subject to the prior notice requirements.

Again, going through that slowly, it would be fruits and vegetables, fish and seafood, dairy products, eggs, raw agricultural commodities for use as food or components of food, canned foods, animal feed including pet food, food or food ingredients, food additives including substances that migrate into food from packaging and other articles that contact food.

Food also includes dietary supplements and dietary ingredients. It includes infant formula and other beverages including alcoholic beverages and bottled water, live food animals such as hogs or elk, and bakery goods, snack foods, and candy.

MR. BARNETT: Did I hear correctly that this list then includes a few more foods than the registration list?

MS. FRASER: No, it's the same list--

MR. BARNETT: It's the same list, okay.

MS. FRASER: --as the registration list.

MR. BARNETT: Okay. You said, and the first panel said, that farms are not required to

register with the FDA. Does that mean that a product that goes directly from a foreign farm to the U.S. is exempt from prior notice?

MS. FRASER: No, that is not correct. Again, the registration rule covered facilities, and there were certain exemptions provided in that rule and in the statute. By comparison, prior notice applies to all foods that are imported or offered for import into the United States regardless of the destination or regardless of the source of the food.

So, here, it is food that is subject to FDA's jurisdiction that is subject to the prior notice requirements.

MR. BARNETT: What if, let's say, tomatoes are transported from Mexico, through the U.S. to Canada, they are not used in the U.S., there is no U.S. importer, there is no U.S. purchaser, is prior notice required on that?

MS. FRASER: Yes, prior notice is required even though the food is not being consumed in the United States or intended for consumption here, it

is still offered for import or imported into the United States before being exported, and under the statute, prior notice would be required. Here, the notice could be provided by the arriving carrier or the carrier that is transporting it.

There is one point I wanted to make about the registration and the prior notice requirements and just about our regulations in general. It is really important to read them in toto and see that you may be subject to one regulation and exempt in another, but just because you are exempt in one does not automatically mean that you would be exempt in another. Each regulation stands on its own, and so people do have to look at it carefully to see whether they are subject or not.

MR. BARNETT: Good point. What foods, if any, are not subject to prior notice?

MS. FRASER: There is one category of foods again, that is foods regulated by the U.S. Department of Agriculture, and that is meat, poultry, and egg products. Those foods products are exempt from the prior notice requirements.

Then, there is a second exemption that FDA is proposing and seeking comment on, and this is food that is brought into the country in a traveler's personal baggage for their personal consumption, and when we say "personal consumption," we are talking about food for their use, their friends, and their family, but if a traveler is bringing in food with the intent of selling it to another or giving it broadly into distribution, then, prior notice would be required.

MR. BARNETT: So, Leslye, so far we have talked about the definition of prior notice, we have talked about which foods. Let's talk now about what information has to be included in prior notice.

MS. FRASER: There is a list that will appear on your screen of the information that we are proposing to be required, and again, much of this information does come from the Bioterrorism Act. We are asking for who is submitting the prior notice. We have authorized a number of people to provide it.

We are asking for who is the submitter, is it a firm or an individual. What is the Customs entry type, is it a consumption entry or an export entry, for example, what is the Customs code. They also have to provide the Customs entry number and line numbers, and this is so that FDA can communicate with Customs, and when the food arrives, be able to tell them that we did receive adequate prior notice.

We need information on the product identity, and there is a detailed list of what that means. It's the FDA product code, and there is seven digits that have to be completed for that. The common usual or market name of the food being imported. The trade or brand name of that food. The quantity including lot numbers or from the largest size down to the smallest, and any other identifiers also have to be provided.

The notice also must include information on the manufacturer and shipper. We need their names, addresses including the country that they are in, and if the food is associated with the

facility that has to register, then, the manufacturer and shipper also have to provide the registration number.

Continuing, we need to know the grower, if that is known. We need to know the originating country of the food, and Ben will talk about that in a little bit, and we need to know the country from which the article was shipped. We also need detailed information of all the importers, the owners, and the consignees, and when I say "detailed," I mean the name, the address, any registration numbers that apply to them.

We need anticipated arrival information including the location of the port of entry and the time of arrival. We need to know the carrier including the standard carrier abbreviation code, and then lastly, we need to know the submission type, is this the initial prior notice that is being provided, is it an amendment to the product identity, and we will talk about that in a little bit, or is it an update to the arrival information, or is it a cancellation of a previously submitted

prior notice.

MR. BARNETT: Let's talk a little bit about timing. There is a window of time in which this can be submitted, the prior notice, not too early, not too late.

Tell us about what that window looks like.

MS. FRASER: That is correct. Under the proposed rule, we are saying that prior notice cannot be submitted more than five days before the food arrives at the port of entry, and that is the limitation that is in the Bioterrorism Act.

And then on the other end, FDA is proposing that the prior notice must be submitted no later than noon of the calendar day before the food arrives at the port of arrival, so there is that window that the prior notice must be submitted within.

MR. BARNETT: Before we go on, let me pause here and mention to our audience, we would like to get your questions phoned or faxed or e-mailed in as soon as possible, so if possible, don't wait until the end. Start sending them in

now. We will accumulate them and then when I am done with my questions here, we will start answering them. So, get the questions in as soon as your can and we will consider them.

George Brush, talk about how the prior notice is submitted. We have been talking about other things like what it has to have in it, and when, but how do you do it?

MR. BRUSH: Prior notice needs to be submitted through FDA's web-based prior notice system. The system will be available 24 hours a day, 7 days a week.

MR. BARNETT: It has to be submitted electronically or can you use paper?

MR. BRUSH: It has to be submitted electronically. Unlike registration, we require an electronic submission for prior notice.

MR. BARNETT: Now, if I am a submitter and I do this electronically, how do I know that you received it?

MR. BRUSH: Well, the system will return an electronic confirmation if the record is

completed to our satisfaction. The record will contain the date, the time, as well as a reference number for your submission.

MR. BARNETT: Now, you said if it's completed to our satisfaction, which leads to the next question, and that is, how am I going to know if it is not to your satisfaction and if you don't accept it?

MR. BRUSH: Well, only accepted submissions will receive this confirmation notification. If you have not received this confirmation notification, then, the FDA has not accepted your submission.

It is important to note that the system will be designed such that it will prompt the user throughout the process to ensure that the mandatory fields and the submission in general are completed accurately.

MR. BARNETT: Will the system tell me that the prior notice that I send in is adequate, and then therefore it is okay for me to go ahead and send the shipment?

MR. BRUSH: No, the system won't return information regarding the evaluation of the submission. The system will only return information regarding a confirmation that the record has been received.

MR. BARNETT: Simply an acknowledgment that you got it.

MR. BRUSH: That's correct.

MR. BARNETT: And that is as far as it goes.

MR. BRUSH: That's correct.

MR. BARNETT: Ben England, let me carry on from that then. One of the purposes of this is to identify those shipments that may need further action by the FDA, an examination or whatever.

When am I going to learn if I am a shipper, whether the FDA is going to be examining my shipment, will I get it as part of this process?

MR. ENGLAND: No, you wouldn't learn that until the article actually arrives at the port of entry, the first place that the article arrives at the U.S.

MR. BARNETT: Let's suppose that I have a mixed shipment, Ben. It contains canned tuna from three different manufacturers. The question is, do I have to enter the same identical information three times or is that one prior notice?

MR. ENGLAND: Well, first, this is a good time to distinguish between a shipment of food and an article of food. An article of food, the proposed rule for prior notice relates to articles of food that are imported or offered for import in the United States, and it is very possible that a shipment, like a 40-foot container, for instance, might contain numerous different articles of food for prior notice's purposes.

That is the example you have here. This is the three different manufacturers for canned tuna, and there is a slide that is on the screen that I think will help to explain this.

If you look at the slide, you will see that on the righthand side, you have got three different manufacturers identified. Even though it is all canned tuna, because of the three different

manufacturers, each of those constitute a separate article of food for purpose of prior notice.

So, a prior notice would have to be submitted for each of those manufacture tuna connections, and it is also true when it comes to the different size cans, you will see that two of the lines are the same manufacturer, but there are 12-ounce cans and 6-ounce cans, and those also would constitute separate articles for the purposes of prior notice.

MR. BARNETT: Let me give you another example. Suppose I import corn and wheat and it is shipped on the same truck. Now, do I submit one or two prior notices for that truckload?

MR. ENGLAND: Here, you clearly have two articles, you have corn and you have wheat, and consequently, you would have two prior notices, and that is not unlike what we have now even with Customs. They would be considered separate articles, separate products for purposes of Customs, as well, for their declaration. You would have to have two separate lines for that.

MR. BARNETT: George, I am assuming, despite the fact that multiple prior notices have to be sent, that the FDA is trying to make this as simple for submitters as possible.

MR. BRUSH: We are doing just that. The FDA is designing the system to minimize the amount of data that is required for each entry. Data that is common to a submission within a food shipment will only be required one time. However, data that pertains to the article or the manufacturer is required for each submission.

MR. BARNETT: Ben, it is interesting to note that prior notice really requires the same information that companies are currently giving to Customs, and so I think a question in people's minds is going to be why am I doing this again for the FDA.

MR. ENGLAND: Well, to begin with, there are a number of things that are different between what FDA would do with the information versus with Customs. As mandated in the statute, prior notice must be submitted to FDA prior to arrival.

Currently, we receive data related to these kinds of entries, but very often it is not transmitted until well after the article has been imported and is, in fact, could be thousands of miles down the road in another state someplace.

So, this allows us to get the information in advance. The purpose would be to evaluate the data in order to determine which articles or which importations we should examine before it comes into the country for the purposes of protecting the public.

Now, as far as Customs and FDA and the different systems, Customs is developing their automated commercial environment, ACE, and FDA is working with Customs to do that, and we plan to continue to do so.

Unfortunately, ACE is not going to be at a stage where they will be able to receive prior notice by December of this year, and their current system, the automated commercial system, ACS, we are not going to be able to get changes made in that quickly enough to do it either.

Consequently, we will have to set up our own system. Before the prior notice requirement, the circumstances that we were dealing with before, it is not unlikely for articles, like the tomato example for instance, that you asked Leslye, where an article could come from Mexico, could cross the U.S. border, go through the United States, and into Canada.

Under our current system, we never even learn about that shipment at all, despite the fact that it is an importation, so under prior notice, we will learn that information.

MR. BARNETT: It seems as though, too, that there is a difference between the purpose of what the FDA needs from this information and what Customs need. There, it is trade and here, it is public health.

MR. ENGLAND: Public health and safety related to potential bioterrorism issues or foodborne.

MR. BARNETT: Right. So, the key things are speed and then catching things early.

MR. ENGLAND: Before they actually get into the United States.

MR. BARNETT: Right, right.

George, I am assuming that we are going to try to design this, so people can use it all the time, as quickly as possible, conveniently as possible.

MR. BRUSH: Well, you know, we are trying to make it as simple as possible. One of the things that we are doing is we are designing a system, such that it is available at all times to receive prior notice submissions. It will be available, as I mentioned before, 24 hours a day, 7 days a week.

MR. BARNETT: We talked, Ben, about the importance of speed from the FDA's standpoint. Why is speed so important?

MR. ENGLAND: As Bob mentioned actually earlier, we believe that the prior notice proposed rule will significantly improve FDA's ability to deter, or to prepare for, or respond to a bioterrorism event or concern, as well as other

public health emergencies that might be related to imported foods, and in order to be able to do that, we are going to need the information in advance. Otherwise, the article would already be in the U.S. before we become aware of it.

Currently, there is no system for FDA to receive in advance this kind of information, so we are kind of in the position where we have to build one independently, which is what George was talking about, the web-based system.

It is also important for us to be able to assess this data in advance, not just to get it when the goods get here, but to be able to get it--

MR. BARNETT: Which requires a little more time.

MR. ENGLAND: --assess it, evaluate it, and then to be able to make a decision as to where we should put resources in order to most efficiently deal with those articles that we need to look at, and then also remove delays from articles that we feel comfortable and confident that we can move them on.

MR. BARNETT: We were talking just now about the difference in outlook or I suppose in purpose between what we need and what Customs needs.

Why don't you talk a little bit more specifically about the information that we are going to require in this regulation versus what Customs requires.

MR. ENGLAND: There is two issues that when people read the proposed rule, they will see that there are some differences, and the first one is our definition of originating country.

The proposed rule for prior notice defines originating country as the country from which the food originates, and it seems like a minor distinction from Customs' purposes, from Customs' standpoint, but I have a slide that will help to explain some of this.

If you look at the slide, you will see that if you assume, for instance, that in the United States, raw carrots are harvested in the U.S., and then they are exported, and then in this

other country, country X, where they are exported to, the product is washed, peeled, and packaged.

Then, it is reimported back into the United States. That article, as it comes back in, would have to have a prior notice related to it, because the originating country, for FDA's purposes, would be the washing, the peeling, and the packaging because that is the activity that has us concerned, that may have us concerned about it.

However, the Customs' country of origin would be the United States of America. So, that is one of the distinctions. This is not new, though, this distinction has actually been around for a period of time, and it has mostly to do with the purposes for which Customs has their country of origin and FDA has its originating country.

Another distinction between Customs and FDA has to do with the way FDA is defining, in the proposed rule, a port of entry, and there is a slide here also that explains that. The proposed rule defines the port of entry as the water, air, or land port at which the article of food is

imported or offered for import into the United States.

A rule of thumb is it is the port where the food first arrives in the U.S. It may not be, in fact, the port where the Customs' entry is filed, and the slide is an example of this.

You will see that if a shipment of food were to come into a seaport in California, and then it would be delivered to Oklahoma where the Customs' entry is filed, for FDA's purposes, the port of entry is the port of arrival, consequently, it is the California port, whereas, for Customs' purposes, they may, in fact, they would count then Oklahoma as the port of entry, so those are two of the big distinctions.

It is worth noting that whenever an article of food crosses the border now, there is always a Customs' entry filed of some kind. It may not be a consumption entry, it could be a warehouse entry or other type of entry, but there is always some kind of an entry that is filed.

We just believe that this definition is

going to assist us in better protecting the public from potential threats of imported foods, so we felt it was important to be able to access the product before it actually is imported into the U.S.

MR. BARNETT: Thank you.

Leslye, shipment plans change, shipment is a dynamic concept, so, you know, you can plan one thing and something else happens.

How can the prior notice be changed after I find out that it isn't going to be the way it is going to be?

MS. FRASER: There are two ways of changing it, and we will talk about the first way, which is amendments, and amendments relate to the product identity. Under the proposed rule, we were concerned about shipments that the person ordering the food may not know with exact specificity what they are going to get the next day, and this really comes with just-in-time shipments or fish fresh catch of the day. I may know that I am ordering fish, but I don't know whether I am going to get

cod or seabass or halibut or whatever.

So, we still would require the prior notice by noon of the calendar day before the food is to arrive, and all of the information pretty much should be known at that point except the exact breakout of what kind of fish. I know I am ordering fish, I am just not sure what kind I am getting.

In that case, they can provide an amendment up to two hours before the food arrives that updates the amount of fish by species that we are getting in. So, that is one of the changes that we are allowing to take into account what isn't known at the day before, but still allows FDA to make decisions on whether we need to be present when the food arrives to make inspections or other examinations.

MR. BARNETT: Now, you talked about the difference between three kinds of fish, but how far can you take that? We talked about carrots before. Suppose it isn't carrots, and now it's squash. Can you amend that?

MS. FRASER: No, you cannot use the amendment process to change the identity of what you are getting. It is really to provide more detail and more specificity on the product you have already ordered.

If you are ordering carrots and then you want squash, then, you would need to have a separate prior notice for the squash.

MR. BARNETT: Ben, let's carry the example a little further. Pretend that on Tuesday morning I order 1,000 pounds of fresh headed and gutted fish from a foreign supplier, and it is supposed to arrive on Wednesday morning, but I don't know exactly what species they are going to send me, I don't know what they can catch, and I don't know whether I am really going to get 1,000 pounds or not.

Now, what do I do?

MR. ENGLAND: This is a good question, and the reason is we have already received this kind of an inquiry particularly from importers who routinely import fresh produce, for instance,

across the land borders, or a product that comes in via air shipment from a close neighboring country, and so their concern is that I may not know how much until I actually load the truck or until the wheels are up on the airplane.

What you would do in those circumstances is that because you are expecting it to arrive on Wednesday and you know it on Tuesday, of course, is that you need to file, submit your prior notice by noon on Tuesday, which is the calendar day prior to the anticipated day of arrival.

When you do your prior notice, you also have to indicate that you have the intent to amend it because you already know that you are not quite sure what the quantity is going to be or what the arrival information is, but there is a lot of information you know already at the time you order it, which is significant, and there is a slide here that points out that the information that is necessary for the prior notice, you already know and it was in your fax.

For instance, you know your supplier and

your manufacturer, you would know your shipper, and you already know the U.S. importer or you could know it, the consignee, and the buyer. In fact, you might be the importer, consignee, and buyer.

You would know already the first five digits of the product code, the characters of the product code. For instance, you said it was fresh, you said it was fish, you said it was head and gutted, you said it was refrigerated, which gets you five of the product code characters.

You would know the quantity, you asked for 1,000 pounds. You would be able to identify an anticipated location or a port of arrival, port of entry where the goods are anticipated to arrive.

You anticipate the next day, and you probably can anticipate when the next day, so you probably have the time of arrival already that you put into the prior notice. You would be able to put the carrier into the prior notice, and you should also have the ability to obtain, probably from your Customs broker is where you would have to get it, but the entry and line numbers and then the

port of entry that might be associated with it, if it turns out to not be the same port where the goods cross the border or where they are first imported.

MR. BARNETT: Then, I submit the amendment to fill in the empty blanks, so the amendment has to be changed.

MR. ENGLAND: That's right, the amendment would then be for the specificity at the time.

MR. BARNETT: And I have got to do that within a certain time frame, right?

MR. ENGLAND: Yes, you have two hours in advance of the actual shipment. Within two hours of the arrival, you have to put that information in.

MR. BARNETT: Leslye, let me add onto that example. Same example, and now at the last minute, the supplier decides to add some shrimp, frozen shrimp to this shipment of fish. Is that okay for an amendment?

MS. FRASER: No, that is not okay for an amendment. Again, that would be changing the

product specificity, and the rationale for not allowing this, FDA really was trying to minimize what information can be changed from the standpoint of allowing us to make inspectional decisions.

If, in your example, we have had an alert or we know that there is potential contamination on shrimp shipments coming into the country, but we didn't have any way of expecting shrimp to come in on that shipment, we would not have had someone available to examine or inspect it, and then if two hours before, we would allow you to say, oh, now, I am adding shrimp, that would not allow us to fulfill the purpose of the Bioterrorism Act.

So, we are really only allowing amendments, and amendments can only be made once, up to two hours before arrival of that specificity. If you have ordered lettuce, you can tell us how much of it was romaine and how much was iceberg, or if you have ordered fish, what was the different kinds of fish, but you can't change completely what the product is.

MR. BARNETT: Okay. Now, we have been

talking about changes that have to do with the quantity or with the nature of the product. Let's talk about changes having to do with timing, about shipping.

I mean let's say the trucker's arrival time has changed because he was held up or he crosses the border at a different location. What about that, can you make changes on that for those sorts of things?

MS. FRASER: The proposed rule again would allow changes for that, and that is an instance where we call an update to the original prior notice, and you can update or you must, under the proposed rule, you would be required to update arrival information if you are coming in at a different port of entry, it may be weather conditions, it may be the road is out, whatever.

If you are coming in either an hour earlier than originally included on your prior notice or up to three hours or three hours or more later than what you originally told us, then, we need to have an update to that prior notice, and

again, that is within two hours of your new anticipated time of arrival.

MR. BARNETT: Okay. So, very quickly to sum up, the difference between an amendment and an update.

MS. FRASER: The difference would be that amendments relate to product specificity, you are updating the type, specific type of product and the quantity. An update is to arrival. What they have in common is that both have to be provided no later than two hours before arrival, and the initial submission, the amendment, and the update all would be provided electronically to FDA's prior notice system.

MR. BARNETT: Okay. Ben, let's shift now and talk about the consequences of not doing this. Okay. What happens if a prior notice is not submitted?

MR. ENGLAND: Well, the statute is clear that if a food is imported or offered for import into the United States, and it lacks prior notice, they don't tell us it is coming, then, the article

is subject to refusal of admission.

That will include at least the article will be held at the port of entry, it will be held there where they arrived, it will be held there where it arrived, and unless the FDA directs that the article be transported into secure storage.

If that happens, then, the importer or the owner or the consignee or the purchaser would be obligated for the transportation and storage costs.

MR. BARNETT: But the importer cannot ship it under bond to his own facility.

MR. ENGLAND: That's right. The article, the statute is clear on that, too. Lacking prior notice, and it is being refused or being held as a result of lack of prior notice, the article cannot be delivered to the importer, owner, or consignee, and that's significant in a sense because virtually every food at this stage is being imported and then released to the importer, owner, or consignee before FDA has made a determination.

But if it lacks a prior notice, then, that is not permitted. The article will either be held

at the port of entry or directed into secure storage. It is also a prohibited act if they import or offer to import food and they fail to comply with the prior notice provisions.

MR. BARNETT: George, what happens if prior notice is submitted, but it is not adequate?

MR. BRUSH: Well, let's talk about inadequate might mean. The FDA's prior notice system will not return an electronic confirmation unless the prior notice submission and its mandatory fields have been completed, so it is not possible, if you have had this electronic confirmation, to have an incomplete submission.

A physical comparison may be required if the submission, if the submission, when compared to the food at the port of entry, is inadequate or incomplete. In this case, the imported food would be denied entry into the United States as an inadequate prior notice.

MR. BARNETT: And, Ben, once again, it would be held?

MR. ENGLAND: Well, in fact, it could be

refused entry, held at the port, and if FDA directs so, it would go into secure storage. If it goes into secure storage, then, the importer, owner, or consignee would be responsible for the transportation and storage costs again, as well as the fact that again if it lacks prior notice, then, it's a prohibited act under the statute.

Now, the timeliness can also be an aspect of inadequacy.

MR. BARNETT: That could make it inadequate, it could be a perfectly good form, but submitted too late.

MR. ENGLAND: That's very possible, and if that's true, then, you are going to end up with a delay because of the timeliness issue, particularly, for instance, if you give me prior notice, give us prior notice on Tuesday and the shipment arrives on Tuesday, at that stage, the prior notice will be inadequate, and it would be subject to refusal and certainly some kind of a review is going to have to be done on it.

MR. BARNETT: Okay. I am getting a little

concerned, looking at the clock. We don't have a lot of time, and I do have a lot of faxes that have come in, so I am going to ask you to, don't talk too fast because we have a translator here, but keep your answers as brief as possible.

Leslye, I wanted to ask you, suppose it isn't timely, and the prior notice arrives too late, and therefore the shipment is being held. Is there any way to rectify that?

MS. FRASER: Yes. The importer or the purchaser or their agent still can provide the prior notice, but again, it has to be noon of the day, the calendar day before arrival. If it's arrived, it still would be held for that day for FDA to be able to examine it, inspect it, and make decisions, and there would be possibly storage costs associated with it.

I wanted to add one thing to inadequate. Your notice also can be inadequate if you have told us you are going to amend it in your initial submission and you fail to include the amendment and give us the update. Then, it also would be

held because we would be looking for a complete, accurate prior notice submission.

MR. BARNETT: Right, it wouldn't be there. Right, right.

Bob, let me ask you, what is the next step with this prior notice regulation, what is going to happen now?

MR. LAKE: Well, first, a complete transcript of today's session will be prepared including French and Spanish translations, and that will be put on FDA's web site.

Again, as with the earlier proposal that we talked about, the most important thing is for the audience and other interested parties to now submit their comments to the Food and Drug Administration.

The comment period will be open for 60 days following publication, which should be shortly, and FDA again will review all of the comments that are submitted to this docket.

It is important that, again, that you include the docket number with your submission, and

for this proposal, the prior notice proposal, the docket number is 02N-0278, and that will assure that it get to the proper place for FDA review.

MR. BARNETT: Well, before we go to the pile of faxes, let me tell our audience you still have some time. We have about 5, 10, 15, about 17 more minutes. We still have time for a few faxes.

One thing we have not gotten yet is a phone call, so you still have time for that. Call us and ask us your question live on the air.

Okay. Let me go through some faxes here.

This one says we have a number of questions that ask that we clarify the role of the submitter, U.S.A. importer, owner, and purchaser. For example, what is the responsibility and liability of the U.S. agent? For example, if prior notice is not made, will there be penalties, will penalties be served on the U.S. agent when the owner is a foreign company?

MR. LAKE: I think that is one on which we would like to get comment, I have a couple of points to make. One, these proposals or FDA's

regulations generally don't make determinations of liability among private parties. That is generally reserved to contracts among those parties.

The real consequence, because of the way the statute is crafted and the proposal is written, is that if prior notice is not submitted, the product simply won't be allowed into the country, so that would have to be remedied by someone in order for the product to come into the U.S.

MR. BARNETT: All right. This one says will this system entirely replace the current requirements for FDA entry information?

MR. ENGLAND: The answer is no, because some of the information that we use for our current admissibility is not in prior notice. Now, I say that, but the other piece to that is that as FDA and Customs works together in the development of ACE, the goal--

MR. BARNETT: Define ACE again.

MR. ENGLAND: ACE, I am sorry, it is the Automated Commercial Environment Customs is--

MR. BARNETT: For the Customs, right.

MR. ENGLAND: And FDA, along with other agencies that interact with imported articles, are in the process of continuing to design a data element set, so that when someone is interacting with the government with regard to international trade, they would only have to submit the information that is in that set, and prior notice data would fall into that set, as would our other data that we used for admissibility.

So, it is not that the prior notice would replace the other data, it is that both prior notice and our admissibility data would, together, go into the other set.

MR. BARNETT: The new system.

MR. ENGLAND: Right.

MR. BARNETT: Okay. It says can the panel please elaborate on imports for export entries, in other words, in bond, transportation, and export or immediate export?

MR. ENGLAND: Elaborate in terms of, I presume, that prior notice is required. If it's a food--

MR. BARNETT: I guess.

MR. ENGLAND: If it's a food and it's being imported, then prior notice is required, and each of those are examples of importation of food.

MR. BARNETT: It says imports for export entry.

MR. ENGLAND: That's right, but they are imported.

MS. FRASER: They start out as imported.

MR. BARNETT: And that is the key, that they start as imports.

MR. ENGLAND: Right.

MS. FRASER: And unlike registration, which is tied for food, it is facilities, but they are making food for consumption in the U.S., prior notice is just tied to food that is imported into the U.S. regardless of the reason.

MR. BARNETT: Here are two of them that I think you covered, but maybe they are worth covering again.

One says will FDA's system respond 24 hours a day, 7 days a week for prior notice?

MR. ENGLAND: It will.

MR. BARNETT: Okay. And the other one, similar, will FDA respond with examinations--well, not that similar--with examinations 24 hours a day, 7 days a week?

MR. ENGLAND: Yeah, that's a good question, and it is a question that FDA has been wrestling with for a period of time. We believe, though, that as FDA learns information about imported products in advance, it will assist us in determining what the impact would be for us to do a 24-hour examination.

Now, if the prior notice information comes in, for instance, and it appears to be adequate, and FDA decides that they want to examine the shipment for its normal admissibility reasons, then, we probably would do that at the importer's premises, not at the port of entry, in which case it could be done when the goods arrive there.

So, it is not a cut and dry FDA will always be at a port of entry. In fact, not all port of entries are even open 24 hours. So, FDA is

continuing to address that, it is worth discussing in comments, submitting that as far as the questioner is concerned, it is worth putting that in the docket.

MR. BARNETT: Here is another one you may want--I am sorry, did you want to--

MS. FRASER: I was just going to add that it is important to understand that the submission of a prior notice and receipt of a confirmation that the notice was adequate and FDA received it and was able to examine it and make an inspection decision on it is different from the admissibility that we currently do.

We still will do that current admissibility, so just because you have submitted an adequate prior notice, doesn't mean that our current laws don't apply.

MR. BARNETT: Again, this is one that you also might want to get comments on. If an import shipment comes in via a carrier that does not use bills of lading numbers as is the case with many land border truck carriers, and no Customs entry

number is known or assigned until the shipment reaches the U.S. border, then, how can a Customs entry or reference number be provided as part of the advance notice?

I will let you answer that one, and then go on.

MR. ENGLAND: It's an excellent question. It definitely belongs in a response to the docket for comments unquestionably. I would also say, though, that as the goods are arriving, somebody knows those goods are coming, and a reference number can be assigned to them. The question is whether they currently are being assigned to them.

So, that is the current thought on it, but we are definitely interested in hearing the comments to the docket.

MR. BARNETT: Let me read the rest of it, I think maybe you covered it. It says if no such number is available, how can one be provided? What alternatives or options are available to the importer for data elements that simply do not exist at the time the prior notice must be submitted?

MR. ENGLAND: Right, and they actually can exist. It is just that the current business process quite normally does not incorporate that number into the way that it runs and the way imported goods move.

For instance, the Customs brokers have the entry numbers, and they can, in fact, provide them or submit the prior notice themselves and designate that number for the food import that is to be anticipated the next day.

That would also be true for non-consumption entries, because they all come in under some kind of a reference number for Customs' purposes, and those numbers can be known, and they can be known in advance.

But again, that is definitely worth comments as far as what the impact of that is.

MR. BARNETT: Okay. Here is one that says is a broker required to submit information to the FDA both via OASIS and through the FDA web site?

MR. ENGLAND: The prior notice system, until the prior notice system, until we are able to

incorporate that into the Customs' ACE system, we will have a stand-alone system, which means the answer is yes, there will be a prior notice submission and the broker would also still have to do their submission through the current ACS system, which is how that is interfaced into OASIS.

That probably sounds like alphabet soup to people who are not used to it. It sounds like it's a broker who understands the answer, but again, these are all worth discussing in the docket. They are all worth putting information into the docket.

MR. BARNETT: This one says can you clarify the need or requirement of lot codes on prior notices? Lot codes can and are assigned electronically at the time of the shipment, which is after or outside of the minimum time window, which is noon the prior day.

MS. FRASER: Again, that is a good comment, and those are the kind of comments that we are interested in receiving, what are the current business practices, what would it mean if the proposed rule went forward as its final and, you

know, why would that information, should that be included in an amendment and why.

MR. ENGLAND: Right. In fact, I even would, that's right, maybe through the amendment as an option, and the other issue is what is being understood as a lot code is probably worth clarifying and which we would do as we go through the comments to the docket.

But it sounds like that is a shipper's lot code. It is where they have designated this is a group of items that I am putting a lot number on, so I can track it through my distribution channel as opposed to a manufacturer's lot code, because I made them in the same batch.

So, you see there is a difference there, and it may be that they are thinking of the distributor lot code.

MR. LAKE: But let me just comment further in terms of the comments that we get back. We are particularly interested in those situations where the business practices don't seem to line up with what these requirements are.

You know, I could understand there would be some resistance to that, but I think what we really need to know in the comments is, you know, how hard is it to adjust the business practices to conform with the prior notice versus FDA's need to have the advance knowledge in order to protect the American people, and that is the equation we have to understand.

MR. BARNETT: Okay. We have probably about five minutes and I have got several. I am going to ask you to, now, don't talk too fast because we do have a translator, but just keep the comments short.

One of them says what happens when the system goes down, are there any provisions for businesses to supply information in an alternative manner?

MS. FRASER: Yes. In the proposed rule, we indicate that if for some reason FDA's prior notice system goes down, then, the importer, purchaser, or their agent can provide the notice either in person, by e-mail or fax to the district

office, the FDA district office with responsibility for the port where the food is coming in, and there will be a web site that lists all the district offices and those ports, so there is provision made there.

MR. BARNETT: Okay. This says if we do prior notice three days prior to the shipment, but in loading, not all of the merchandise will fit on the truck, can the notice be amended?

MS. FRASER: Yes, as long as it is the same product coming in, then, they would amend the quantity and the product specificity, yes.

MR. BARNETT: Okay. This is the last one I have in this pile. It says to what extent must each amendment recapitulate the information in such notices that don't change?

MR. BRUSH: You would only be amending just that piece of new information. We are not asking you to go back and amend the entire submission.

MR. ENGLAND: So, the system would keep the prior information.

MR. BRUSH: Oh, absolutely, absolutely.

MR. BARNETT: We have a phone call. Our first phone call is from Seattle, Washington. Seattle, you are on the air, go ahead.

CALLER: Good morning. This is a follow-up actually on the lot code question that was raised a moment ago. In the current just-in-time environment, it is not unusual for a manufacturer to be producing a product that is in the case of, say, canned goods assigned a particular lot code number, that it, too, would go in directly from the end of the processing line onto a conveyance, that then heads for the United States.

This is particularly true in the air and land border truck environment, but it applies to anything that is handled on a highly expedited GIT basis. This is another instance in which required duty elements simply may not exist at all 24 hours prior to the shipment's arrival in the U.S.

MR. BARNETT: Thank you, caller.

MR. ENGLAND: And I would say this goes

back really to the question that was on the fax, and we would have to reevaluate, for instance, whether it is the kind of a data element that could be amended. We will just have to look at that again.

MR. LAKE: But also--this is to get back to my earlier point--companies that can foods have a schedule for how they do their coding, and it may well be that they could get that, you know, that someone could get that information in advance and provide it even though the cans won't really come off the production line until later.

MR. BARNETT: Okay. Well, having no more phone calls, the pile of faxes is exhausted, and we are exhausted, I will thank you all for a very good discussion, and I thank you for watching and for your good questions.

We hope you found this broadcast interesting and I hope you found the information in it useful. Again, we really want your comments on these two regulations, so, please, send them to our Dockets Management Branch.

In just a moment, we are going to show that address on your screen again, as well as the FDA Bioterrorism web site address where you can get information on future broadcasts.

Until next time, then, this is Mark Barnett.

[Whereupon, at 2:55 p.m. the teleconference was concluded.]

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CERTIFICATE

I, **ALICE TOIGO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

Alice Toigo

ALICE TOIGO